Kansas Department of Health and Environment
Procedures for Institutional Review Board
Version 9.0
Revised October 27, 2004

1. Scope of activity

a. The Kansas Department of Health and Environment IRB #1 (IORG0000646, IRB00000986) shall review research protocols involving human subjects that shall arise out of the appointed activities of this state agency. Review may include research of other institutions or agencies if some or all funding is supplied by KDHE, or involves a local health department.
b. The Office of Human Research Protections (OHRP) provides that certain studies may be exempt from IRB oversight; however, federal regulations provide for IRB institutional authority even when a study is exempt from federal oversight [46.101(b)] A researcher may apply to the board chair (or designee) for an exemption from IRB review on these grounds. Alternatively, the chair (or designee) may request the full board to make a determination. A study may receive an exemption from federal oversight but not from KDHE oversight, exemption from both, or exemption from neither.
c. Studies which meet OHRP guidelines for exemption include:
    i. Survey or interview where neither personal identifiers nor numbers which link to personal identifiers are used and where release of results would not place any participant at any risk (civil, criminal, financial, personal);[46.101(b)(2)] and
    ii. Research using existing data or records which are public information or which does not contain identifiers or links to identifiers. [46.101(b)(4)]
    iii. Other types of studies not common within this agency may meet OHRP guidelines for exemption. A researcher may request exemption based upon review of exemption guidelines from OHRP. [46.101]

2. Statement of principles for the protection of human subjects

a. This agency recognizes the vulnerability of all persons to exploitation, whether by accident or intent, by persons or institutions conducting research.
b. No research, whatever its benefit to society as a whole or to this institution in particular, justifies subjecting persons to risks to health, emotional well-being, or social well-being without the complete knowledge and understanding of such persons as to the risks and potential benefits (both personal and societal), and their complete and willing consent to those risks, and an understanding that consent may be withdrawn at any time without penalty other than loss of that benefit the person may have obtained arising from continued participation.

c. In situations in which the risk to individuals exceeds minimal risk, the benefit to be gained by that risk exposure must substantially outweigh the risks imposed by the research.
d. "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 46.111(a)(2)
e. No consent may be obtained under any circumstance which might be construed as duress. Refusal to give consent for research participation shall not in any way threaten the well-being, or opportunities of an individual, since this would constitute duress.
f. Certain groups are recognized as possessing heightened vulnerability to exploitation 46.111(a)(3) including non-citizens, persons with impaired English language skills, prisoners, children, and the mentally impaired. The board may choose to require protections in excess of federal requirements for persons in any of these categories, especially if the study involves greater than minimal risk. In the case where the person is a child or mentally impaired, a parent or legal guardian of the research participant must cosign the consent.46.111(b)
g. Fetal research is outside of the scope of this review board.
h. Signed consent by a participant is the consent to be exposed to both the potential risks and the potential benefits of the investigation. The consent does not relieve the investigator of the responsibility to minimize those risks to the extent possible. 46.111(a)(1) In signing the consent, the participant does not waive his or her right to due process or compensation in the event of harm. 46.116 In receiving the consent, the investigator does not guarantee compensation in the event of harm.
i. Restrictions on participation in the investigation must be clearly stated in the research protocol. 46.111(a)(3) The IRB shall review restrictions on enrollment and ensure that such restrictions are appropriate to the outcome of the investigation and thereby do not represent discrimination against any person on the basis of race, ethnicity, religion, gender, age, or sexual orientation.
j. The investigator is responsible for protecting the confidentiality of participants. Consent for release of information which specifically identifies a person must be separately obtained and the content of the information to be released must be known and understood by that person. Furthermore, the investigator is responsible for preventing accidental release of confidential information. Protection of confidential data in all forms whether written or electronic is required. The IRB may require the investigator to specifically state the date on which all personal identifiers will be destroyed.

3. **Compatibility with federal guidelines** At the time of the revision of this procedure, standards for the activity of this IRB were written to meet requirements of Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects. Revised November 13, 2001.

4. **Board Structure**
   a. Members of the IRB
      i. Shall not be fewer than 5 [46.107(a)] nor more than 10;
      ii. Shall include both males and females; [46.107(b)]
      iii. Shall have at least one person not employed in KDHE, nor related to a person employed by KDHE; [46.107(d)]
      iv. Shall have at least one person who is a scientist and at least one person who is not a scientist. [46.107(c)]
   b. Appointment to the Board
      i. The Chair of the Board shall be appointed by the Director of the Division of Health;
      ii. A replacement member of the board must be recommended to the Chair by an existing board member, and appointed by the Chair at his or her discretion.
      iii. Members are appointed to serve from January 1 through December 31, or through that part of the year remaining at the time of appointment to the board. Annually, the board Chair shall automatically renew the appointment of board members who are satisfactorily serving the board. The Chair may remove a member at the end of an annual term, or at any time during the term subject to approval of the majority of the board.

5. **Chair** - The Chair shall be responsible for
   a. Calling the board into session;
   b. Scheduling new research protocols to be reviewed;
   c. Ensuring that the responsibilities of the board are met during the review of each research proposal;
   d. Designating one person to serve as administrator;
   e. Providing guidance for logistical management of the board to the administrator;
   f. Assigning board members to follow-up or contact an investigator;
   g. Notifying all members of actions taken by the board or taken by board members acting for the board;
   h. Ensuring that federal requirements for registration and assurance are met;
   i. Ensuring that board members are adequately trained;
   j. Communicating with OHRP and agency administration regarding IRB matters.

6. Conflict of Interest
   a. Conflict of interest shall exist when a member of the board

i. Is responsible for conducting any part of the investigation;
ii. Is part of the research team (i.e., assisted in the research design in a role other than as a reviewer, or participated in recruitment of participants, or collected data from participants); or
iii. Has contributed to the research to an extent that he or she might reasonably be included as an author for a scientific publication arising from the research (whether or not a publication is planned and whether or not inclusion of his or her name as an author is planned).

b. A member of the IRB who has conflict of interest with a protocol being reviewed shall not vote regarding the acceptance of that protocol, but may provide information to the board as a researcher once he or she has stated before the group that a conflict of interest exists and he or she shall not be voting. [46.107(e)] In the event that the chair has a conflict of interest, he shall name another board member as acting chair during the review of that protocol and likewise shall not vote.
c. If a board member is unsure whether his or her involvement constitutes a conflict of interest as defined above, the Chair shall determine whether a conflict of interest exists. Otherwise, each board member is responsible for determining for himself or herself whether a conflict of interest exists and notifying the chair when such a conflict of interest exists before review of that protocol begins.
d. If a member of the board is concerned that another member has an unreported conflict of interest, the concerned member may raise the concern with the Chair privately or may raise the issue before the entire board for discussion. Following any discussion, the Chair shall decide whether a conflict of interest actually exists.

7. **Establishing a session**
a. All members of the board shall be notified of the time and place of each scheduled board meeting at least seven days before the scheduled date.
b. Sessions of the board shall be established on an as needed basis.
c. A majority of the board members must be present and at least one member of the board whose primary interest is not scientific must be present in order for the review to proceed. [46.108(b)]
d. In the event of the absence of the chair, the chair shall arrange for another member of the board to act as chair in his or her absence.
e. All members shall receive all relevant documents at least three days prior to review.

8. **Documents required for review**
a. Researchers who are requesting a project review should contact the chair or the IRB administrator. The researcher will be given

informational document and may be asked to complete summary information on a form.

b. Unless specifically determined not to be applicable, all researchers shall submit the following documentation for both new and continuing review:
    i. Protocol;
    ii. Grant application;
    iii. Written consent forms;
    iv. Data collection instruments;
    v. Any documents to be used in participant recruitment;
    vi. Results of reviews by any other IRB board; and
    vii. Any other documents requested by the Board

9. **Study liaison -** For each research proposal submitted, the chair of the IRB shall assign a member of the board to act as liaison for study. This board liaison shall a) ensure the completion of required documentation, b) be notified in the event that changes in protocol or risk occur during the course of the investigation, and c) act as reviewer for periodic (e.g., annual) reviews of research approval, d) ensure compliance with restrictions imposed by the board, and e) notify the investigators of actions by the board which affect their research.

10. **Informed consent**

a. Each informed consent form shall have a revision date printed on it. Informed consent shall be obtained from all participants in all investigations unless the board determines that the research meets conditions for waiver and agrees to the waiver. The board may waive the requirement for informed consent (or alter some or all of the required elements of informed consent) if all of the following conditions are met:
    i. The researchers involves no more than minimal risk; and
    ii. The waiver or alteration will not adversely affect the rights and welfare of the research subjects; and
    iii. The research could not practicably be carried out without the waiver or alteration; and
    iv. Whenever appropriate, research subjects will be provided with additional pertinent information after participation. 46.116(d)(1-4)

b. The board may waive the requirement for written consent (i.e., a signed consent form from each participant) in any of the following circumstances:
    i. Research involves not greater than minimal risk and no procedure is being performed for which consent is normally required outside of research. 46.117 (c)(2)
    ii. In research in which breach of confidentiality is the primary risk and the only research linking the subject to the research is the consent form. In this case each subject of the research shall be

c. Should the board agree that waiver of informed consent or written consent is appropriate, the reasons for the waiver shall be documented in the minutes.
d. Informed consent shall be in writing, signed by the participant, and a copy shall be given to the participant. [46.116(a)] Oral consent which does not involve obtaining the signature of the participant or their legal representative is not acceptable unless the board has determined that the study meets OHRP approved criteria for waiver of written consent as noted above. [46.117(a)(1-2)]
e. The investigator must ensure that the person fully understands the study and the nature of his or her consent and right to withdraw at any time. An interpreter must be used if the research subject lacks English proficiency.
f. Characteristics of the informed consent document are as follows:
    i. Simple language explaining
        1. That consent is consent to participate in research;
        2. The purpose of the research;
        3. Duration of participation;
        4. Procedures to be followed; and
        5. Identification of experimental procedures. [46.116(a)]
    ii. Description of reasonably foreseeable risks or discomfort to the participant;
    iii. Potential benefits, to participant or to others, which may be expected from the research;
    iv. Any alternative procedures or treatments available to the participant;
    v. Description of confidential information which will be recorded and maintained regarding the subject;
    vi. If greater than minimal risk
        1. Availability of compensation if injury occurs, and
        2. The nature of available treatments for any injury that occurs;
        3. Contact persons for
            a. Reporting injury arising from the research, and
            b. Obtaining answers about research and participant rights;
    vii. Statement that
        1. Participation is voluntary; and
        2. Refusal to participate or termination of participation will not result in penalty or loss of benefit (except that which might have arisen as a direct consequence of treatment offered through participation), and
        3. Participation may be terminated at any time;
g. When appropriate the consent shall also contain the following:

i. Possible occurrence of unforeseen risks which could potentially harm the participant (and fetus or embryo if participant is pregnant);
ii. Circumstances which may result in the investigator terminating the research;
iii. Any additional costs that may result from participation;
iv. Potential consequences of participant early withdrawal from the research, and how such termination will be conducted to minimize any risk to the participant;
v. Statement of the impact of new information or findings which could affect the participant's willingness to participate;
vi. The approximate number of persons to be enrolled in the study. 46.116(b)

11. **Expedited Review**

a. Initial review using an expedited procedure may be conducted by a board member approved by the chair to conduct expedited review, for the following types of studies performed on adults as described in Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure (available at the OHRP website):
   i. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves;
   ii. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis);
   iii. Collection of data from voice, video, digital, or image recordings made for research purposes;
   iv. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies; and
   v. Prospective collection of biological specimens for research purposes by noninvasive means.
b. Other types of expedited review even if approved by federal regulations and OHRP policy (e.g., blood collection) are not approved for expedited review by this board since review of these types of protocols are not sufficiently common to ensure adequate protection of human subjects using expedited review.
c. Research involving children will come before the full board.
d. Expedited review may not be performed for any study not designated as minimal risk.[46.110]

e. Continuing review using expedited procedures of a study previously review by expedited review is permitted unless changes are being proposed which would place the study outside one of the categories above. Continuing review by expedited procedures may be used for studies previously approved by the entire board under the following circumstances:
    i. The research is permanently closed to the enrollment of new subjects; and all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
    ii. No subjects have been enrolled and no additional risks have been identified; or
    iii. The remaining research activities are limited to data analysis.
f. Procedures being approved by expedited review should be referred to the full board if they:
    i. Are found on examination to fall outside the scope of expedited review authority;
    ii. Raise concerns about human protection which the reviewer feels are complicated or unusual; or
    iii. Poses potential risk to the agency.
g. The reviewer performing an expedited review shall provide written findings and conclusions to the IRB administrator along with all protocol documents for filing. At the next full board meeting following an expedited review, the reviewer shall briefly describe each approved protocol to the full board.

12. **Exemption of protocols from IRB review**
    a. No researcher should determine that a planned data collection or research intervention is exempt from IRB oversight.
    b. All requests for exemption should be referred to the chair (or designee) to determine whether exemption from OHRP is legitimate, or whether KDHE has a compelling interest in reviewing the project even if otherwise exempt. Requests must be written and must be submitted through a New Project Request Form and a Request for Exemption Form.
    c. When the board chair (or designee) determines that a protocol is exempt from IRB review, a signed IRB Report of Action Form should then be forwarded to the IRB administrator including the specific reason for exemption. The administrator shall record and file this information.

13. **Research involving children** - For research enrolling children as research participants, additional requirements must be met as follows:
    a. Researchers must clearly state to the board the extent to which children will be involved in the study, and specifically obtain consent from the board for research which will involve children as participants.

b. The board will require review of research (normally exempted for adults), which involves survey, interview or observation, although exemptions may be given after full board review. 46.401(2)(b)
c. Any child who is capable of understanding the nature of the research in which they are being asked to participate must agree to participate (i.e., provide assent). The child's assent to participate shall be witnessed by the person granting permission (e.g., parent or guardian). In obtaining permission from the parent or guardian, the researcher must make sure that the person granting permission is also documenting that either
    i. The child can give and has given assent, or
    ii. The child cannot reasonably provide such assent.
d. Factors to be weighed in considering a child's capability to provide assent include the age, maturity, and psychological state of the child. 46.408(a) In the research protocol, the researcher must state the procedure to be used for determining a child's capability of providing assent. When assent is waived because a child is incapable of providing it, the researcher must record how that determination was made in sufficient detail that the board could concur with the decision if reviewed.
e. The board will determine the level of risk posed by the study and the potential benefit of the study to the participants and society. Risk/benefit will fall into one of the following categories:
    i. Minimal - permissible; 46.404
    ii. Greater than minimal with anticipated direct benefit to participants. This may be permissible if:
        1. the risk is justified based upon the anticipated benefit, and
        2. Benefit is at least as great as that presented by alternative approaches; 46.405
    iii. Greater than minimal without direct benefit to participants but likely societal knowledge benefit may be permissible if:
        1. The risk represents a minor increase over minimal risk;
        2. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; and
        3. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects disorder or condition. 46.406

        At this risk/benefit level, consent from both parents is required unless the second parent is "deceased, unknown, incompetent, or not reasonably available." 46.408(b)

iv. None of the above--research falling outside those above will be outside the scope of this IRB to approve; however, if the IRB feels that the research is important and falls within the goals of the institution, the board may refer the research to HHS for review. [46.407]

f. In the event that a researcher has reason to believe, incidentally or by study design, that a child is
   i. Not reasonably protected by parent or guardian permission (e.g., an abused child), or
   ii. The child is a ward of the state,

   the researcher shall consult with the board chair to determine an OHRP-approved mechanism for enrolling such a child in a study.

14. Research involving Prisoners

a. This institution shall not routinely review research involving prisoners.
b. In the event that review of research involving prison participants is necessary, the board will be convened with a prisoner representative present as required by federal regulations, [46.304] and applicable regulations related to review of research involving prisoners shall be reviewed in detail before the research is presented.

15. **Conducting the Board**

a. The chair shall designate an acting secretary for the session if the IRB Administrator is absent. The Administrator or secretary shall take complete minutes and update the log as necessary.
b. Record shall be made of board members present and absent including determination that greater than 50% of active board members (never fewer than three persons) are present before proceeding. Furthermore, at least one person whose interests are non-scientific must be present. Members may participate in the board by telephone if they have received materials to be reviewed in advance of the board meeting.
c. If necessary, actions shall be taken to
   i. Adopt changes in the procedures governing the board in order to maintain compliance with regulations governing the functioning of an IRB and to ensure the smooth functioning of the board, or
   ii. Recommend replacement board members who have become inactive or who have requested dismissal from the board.
d. A log shall be maintained of investigations with the following information:
   i. Date of review;
   ii. Project name;
   iii. Presenters;
   iv. Bureau or agency conducting the study;
   v. Disposition of the study (approval status);

vi. Designated board liaison;
vii. Duration of approval.

e. Review of research proposals shall be conducted one at a time before the entire board. In order for a proposal to be presented, the presenter must be one the investigators on the project who has a thorough understanding of the research and human studies issues which the investigation raises, and documentation must be complete.

f. The investigator shall present the protocol (including an explanation of the human studies issues involved), and then receive questions from the board. The board shall then determine the following:
   i. Whether the proposed research falls within the scope of the institution's mandate;
   ii. Whether the proposed research violates any federal or state laws; 46.101(f)
   iii. Whether the proposed research violates accepted standards of professional conduct or community norm;
   iv. Whether selection criteria for participation represent discrimination not justified by the research needs of the study;
   v. Whether the level of risk to which participants will be exposed is
      1. minimal; 46.102(i) or
      2. greater than minimal, and if greater than minimal, determine the level of risk;
   vi. Whether the level of risk exceeds the potential benefit; 46.111(a)(2)
   vii. Whether risks have been truly minimized; 46.111(a)(1)
   viii. Whether the proposal adequately protects the confidentiality of participants; 46.111(a)(7)
   ix. Whether established requirements for informed consent are adequately met by the research proposal; 46.116(a-b)
   x. Whether procedures and documents prepared for informed consent adequately inform the participants of the risks and benefits while ensuring their voluntary consent; 46.111(a)(5)
   xi. Whether the proposed mechanism of obtaining consent will place participants under duress; 46.116
   xii. Whether collection and use of data will pose any unanticipated hazards for participants;
   xiii. Whether highly vulnerable populations will be protected and procedures followed which are consistent with their full protection; and 46.111(b)
   xiv. Whether additional procedures for monitoring data generated by the study will be required to ensure the safety and health of participants. 46.116(a)6)

g. Following the completion of review of each proposal, the board shall:
   i. notify investigators in writing of the board's decision and of the board liaison with whom they should communicate further; 46.109(d)
   ii. document the reasons for the boards decision; 46.109(d)

iii. maintain with the log copies of documents sent to investigators; 46.115(a)(4)

iv. maintain on file for a minimum of 3 years after completion of the study copies of the protocols reviewed and any changes. 46.115(a)(1)

16. **Voting**

a. The Chair shall conduct the vote. Vote may be by voice or show of hands.
b. Each member of the board present (including the chair) shall have a single vote.
c. A board member may not delegate his or her vote to any other person. A board member absent from the board review has no vote during that review session.
d. Any member who has excused himself or herself from the vote based upon conflict of interest will be considered to have abstained.
e. In the circumstance where the Chair has excused himself or herself from voting based on a conflict of interest, the person he or she has selected to be Acting Chair shall conduct the vote. However, in delegating the responsibility to preside over the vote, the Chair does not delegate his or her vote.
f. The chair may dismiss the investigator before deliberation of the board. Decisions of the board require that a majority (>50%) of the board members present agree on the decision. The board secretary shall record the vote in the minutes including the number of persons who voted total and for each response category (yea, nay, abstain). The names of persons voting nay shall be recorded in the minutes.

17. **Decisions of the board**

a. The board may make any of four decisions following protocol review:
    i. Approved - includes statement of any special circumstances or limitations that the board believes have been mutually understood and accepted. This may not be used when substantive changes to protocols or consent forms are required. This decision requires no further action by the board for research to begin; 46.109(d)
    ii. Conditionally Approved - This will include statement of changes required in the protocol. 46.109(d) Obtaining approval to proceed requires a second review once those conditions are met;
    iii. Not Approved - includes statement of reasons for disapproval and explanation on how the decision can be appealed. 46.109(d) This condition implies irreconcilable differences between the board and the researcher. Examples of such differences would include the following:
        1. Research outside the scope of the institution;
        2. Research outside the scope of the board to review;

3. The researcher is unable or unwilling to make changes in the protocol of a nature that would protect human subjects to an extent which satisfies the board.

iv. Deferred - incomplete information available for review (includes statement of documentation which must be completed before review can proceed).

v. Exempt – the board believes the research is exempt from the federal policy for the protection of human subjects.

b. The Board Administrator will prepare a form which identifies the study, board decisions, any changes required, instructions to return for repeat review if changes are substantive, and detailed minutes. A copy will be provided to the researcher and to the file after being signed by the chair. The research will be responsible for communicating with any other parties (e.g., funders) regarding the decision of the board.

c. The form which the researcher receives shall clearly state that no protocol changes which have not been reviewed and approved by the board may be instituted without additional board review unless a change is made emergently to prevent harm to a research subject. In the case of an emergency protocol change, the board should be notified immediately and further recruitment to the study should be halted until permission to continue has been received from the board.

18. **Continuing Review**

a. Once approved, research must be reviewed no less often than annually. 46.109(e) The board may choose to conduct continuing review for project in less than one year. The decision to review a protocol in less than one year is likely to be made in any of the following circumstances:

i. The researcher has had problems with compliance with board decisions in the past;

ii. The board feels that unanticipated risks may arise and would it like to review outcomes for the first subjects enrolled; or

iii. The board feels that the potential benefit is not much greater than the potential risk; or

iv. The board decision involves the dissent of some members.

b. At the time of initial approval, the board will notify the researcher of the duration of approval. The researcher must ensure that he or she schedules a continuing review with the board or the designated board liaison prior to the expiration of approval.

c. Presentation of information for continuing review should include the following:

i. A brief review of the research, its purpose, and methods, and a full description of procedures or data collection which pose risk to the participants, whether risk to health or confidentiality;

ii. A review of study progress including number of subjects enrolled;

iii. Adverse or unanticipated events which have occurred which may reflect on the risk to participants, and any reasons for any person's withdrawing from the study;
iv. Review of complaints received about the study;
v. Proposed modifications to the protocol;
vi. Any new results from this study or other studies which may reflect upon the risk to the participants;
vii. Review of the current informed consent document which is in use.

d. The board may require external documentation for continuing review (i.e., not from the researcher) in the following instances:
    i. The researcher has had problems with compliance with board decisions in the past; or,
    ii. The institution has received one or more complaints about the research project under review;
e. Any change in protocol or documentation must be reviewed and approved by the board before implementation;

19. **Problems**

a. Researchers will be instructed to contact their board liaison in the event of any of the following:
    i. A breech in protocol which might potentially infringe on participant rights;
    ii. A breech in confidentiality;
    iii. A research participant experiences harm as a consequence of participation; or
    iv. Additional risks or unanticipated circumstances that may pose risk are identified.
b. In the event of any of the above occurrences, the liaison shall investigate and discuss findings with the Chair, Administrator, Agency Official. OHRP will be notified if substantial problems are confirmed.
c. After considering the nature of the problem, the potential threat to research participants, the severity of harm which occurred, the promptness with which the problem was identified and reported by the researcher, the risk/benefit to participants of terminating the research, and the reason why the problem occurred, the board may act in one of the following ways:
    i. Allow the research to continue under close observation;
    ii. Temporarily suspend research activity until risks have been minimized to the extent that the research can proceed safely;
    iii. Terminate the research.

20. Appeal

a. If a researcher presents a protocol to the board which is rejected, he or she may do any of the following [46.109(d)]:

i. Request by letter another review by the board based upon changes made to the protocol,
ii. Request by letter an opportunity to present the protocol and discuss the board's decision in the presence of the Division Director and Board Chair.

b. If the Chair and Division Director feel that the board should re-hear the research protocol, the Chair shall arrange a new hearing within one month. In this circumstance, a re-hearing does not require the protocol to be changed prior to re-presentation. However, if board members were absent from the initial hearing, the board Chair shall make every attempt to arrange a time and place within that one month period when all board members may be present for the re-hearing.
c. If the Division Director and Board Chair can identify no grounds upon which to have the board reconsider the protocol, no further action by the board is required. However, the researcher may request again to present the proposed research after one year from the date of initial review.

21. Revisions to these procedures

These procedures may be amended between meetings with the approval of all members of the board, or with majority vote during a meeting when a quorum is present.